



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

April ²³ 17, 1997

WARNING LETTER
CIN-WL-97-324

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Allen K. Vrable, President
Vrable Healthcare Services
3248 Henderson Rd.
Columbus, OH 43220

Dear Mr. Vrable:

During a March 19-28, 1997 inspection of your liquid medical oxygen transfilling facility, located at the above address, our investigator documented serious deviations from the Current Good Manufacturing Practices Regulations (Title 21 Code of Federal Regulations, Part 211). These deviations cause your drug product, Oxygen USP, to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Specific observations made during the Inspection include:

- (1) Failure to establish and maintain adequate Batch Production and Control Records in that: (a) no record contains documentation that prefill visual inspections are conducted; (b) no record documents supervisory review and release; and (c) several batch records were improperly altered by persons other than the filling operator.
- (2) Failure to provide or document training of employees in standard operating procedures, good manufacturing practices, or the test methods used in the analyses of incoming liquid oxygen (LOX).
- (3) Failure to assure incoming liquid oxygen is of suitable purity and strength in that:
 - (a) Certificates of Analyses for the acceptance of incoming liquid oxygen fail to include: the specific identity of the test method used and a statement that the oxygen is "Produced by air-liquefaction".

Note: An alternative method of meeting this requirement would be to maintain on file separate letters for each supplier stating this information. If the oxygen is **not** produced by air-liquefaction, a separate analysis must be performed for Carbon monoxide and Carbon dioxide.

- (b) assay results are not always documented or do not always bear documentation that they were witnessed by your employee who was taking receipt the oxygen.
- (4) Failure to maintain an adequate Master Production and Control Record in that the current records do not identify the product name, specifications for purity and test methods to be employed.
- (5) Failure to establish written operating procedures for the following: (a) receipt, testing, acceptance and rejection, and transfilling of liquid oxygen from vehicle mounted dewars to cryogenic home units; (b) product reconciliation; (c) customer complaints; or (d) employee training in SOPs, Good Manufacturing Practices, and testing procedures.
- (6) Failure to assay any filled cryogenic home units which have just been serviced or sent out for servicing.

The inspection also documented that your cryogenic home units are misbranded under the following sections of the Act:

502(f)(1) in that it is regarded as a prescription drug and the labeling fails to bear the prescription legend "Caution: Federal law prohibits dispensing without prescription".

502(g) in that its labeling fails to indicate whether or not the oxygen has been produced by the air-liquefaction process as required by the United States Pharmacopeia (USP 23).

502(o) in that it was manufactured in an establishment not duly registered under section 510 of the Act and the article has not been listed as required by section 510(j).

Drug establishment registration and listing information and forms may be obtained by writing to:

Consolidated Forms and Publications Distribution Center
Washington Commerce Center
3222 Hubbard Road
Landover, Maryland 20785

The above described violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that you adhere to all current regulations applicable to your operations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising Health Care Finance Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these violations. Failure to achieve prompt correction may result in regulatory action without further notice. These include seizure and/or injunction.

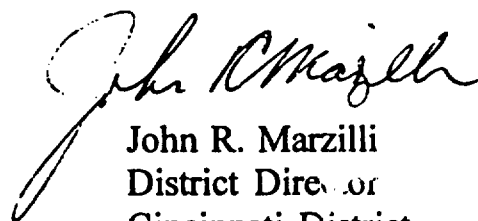
Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct these violations. Your response should explain each step you have taken to correct the noted violations, including steps taken to prevent recurrence of similar violations. Include any documentation showing these corrections.

If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the U.S. Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202-1097, to the attention of Charles S. Price, Compliance Officer. Any questions regarding this letter may be directed to Mr. Price at telephone (513) 684-3501.

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Sincerely,

A handwritten signature in cursive script, appearing to read "John R. Marzilli".

John R. Marzilli
District Director
Cincinnati District

cc: Daniel L. Carey
Vrable Healthcare Services
3248 Henderson Rd.
Columbus, OH 43220